

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

<b>IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION</b>	<b>MDL No. 2875</b>
<b>THIS DOCUMENT RELATES TO:</b> <i>Roberts v. Zhejiang Huahai Pharmaceutical Co. Ltd., et al.,</i>  Case No. 1:20-cv-00946-RMB-SAK	<b>HON. RENÉE MARIE BUMB</b>

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**PLAINTIFFS' BRIEF IN SUPPORT OF MOTION TO EXCLUDE  
DEFENSE EXPERT DR. GREGORY DIETTE DUE TO UNTIMELY  
DISCLOSURE OF GENERAL CAUSATION OPINION**

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NIGH GOLDBERG RASO &  
VAUGHN, PLLC  
*Attorneys for Plaintiffs*  
14 Ridge Square NW  
Third Floor  
Washington, D.C. 20016  
Tel: 202-792-7927  
Fax: 202-792-7927

On the Brief:  
Daniel Nigh, Esq.  
Kathryn Avila, Esq.  
Stephanie Iken, Esq.

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## **INTRODUCTION**

Plaintiffs respectfully move to preclude the prejudicial, untimely, and unjustified expert report and deposition testimony of Defense Expert Dr. Gregory Diette, MD, MHS under the Federal Rules of Civil Procedure 16(f) and 37(c)(1). Although designated as a specific causation expert for Mr. Roberts, Dr. Diette's report (Ex. A) fails to address any facts specific to Mr. Roberts, such as his medical history, the details of his NDMA exposure, the timing of his cancer diagnosis, or the course of his treatment. In fact, Dr. Diette's report does not mention Mr. Roberts at all. Instead, his report presents broad critiques of the epidemiological literature and applies the Bradford Hill criteria.

Dr. Diette's opinions focus solely on whether NDMA-contaminated valsartan is capable of causing liver cancer in general, not whether it caused Mr. Roberts' cancer specifically. Even Dr. Diette concedes that nearly his entire report does not relate to specific causation. Dr. Diette's opinions are textbook general causation opinions, already the subject of coordinated expert discovery and *Daubert* proceedings in this MDL. To permit them now, under the guise of specific causation, would violate the Court's scheduling orders and prejudice Plaintiffs by relitigating an issue that has already been addressed and closed.

Accordingly, Plaintiffs respectfully request that the Court preclude Dr. Diette from offering his untimely general causation opinions.

### **APPLICABLE LAW**

Where a party fails to disclose an expert in accordance with scheduling orders, exclusion of the expert's opinions is appropriate under both Federal Rules of Civil Procedure 16 and 37. Federal Rule of Civil Procedure 16(f) authorizes courts to issue "any just orders" if a party fails to comply with a scheduling or pretrial order.<sup>1</sup> Federal Rule of Civil Procedure Rule 37(c)(1) provides that a party who fails to disclose an expert or supplement in accordance with Rule 26 is not permitted to use that information "unless the failure was substantially justified or is harmless."<sup>2</sup>

Courts routinely exclude late expert reports that contain new opinions not previously disclosed, particularly when they would cause prejudice or disrupt the case schedule.<sup>3</sup> Courts apply a five-factor test to determine whether exclusion is appropriate:

- (1) surprise to the opposing party;
- (2) ability to cure the surprise;

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<sup>1</sup> *Fed. R. Civ. P.* 16(f)(1)(C).

<sup>2</sup> *Fed. R. Civ. P.* 37(c)(1).

<sup>3</sup> See *Yeti by Molly, Ltd. v. Deckers Outdoor Corp.*, 259 F.3d 1101, 1106 (9th Cir. 2001); *Campbell v. United States*, 470 F. App'x 153, 157 (4th Cir. 2012) (affirming exclusion where plaintiff failed to comply with Rule 26(a)(2)).

- (3) likelihood of trial disruption;
- (4) explanation for the failure; and
- (5) importance of the evidence.<sup>4</sup>

Federal Rule of Civil Procedure Rule 16(b) authorizes courts to issue scheduling orders to govern deadlines, including those for expert discovery.<sup>5</sup> Courts have broad discretion to enforce those orders and may exclude evidence as a sanction.<sup>6</sup> These rules are designed to secure “the just, speedy, and inexpensive determination of every action.”<sup>7</sup>

### **TIMELINE**

From the outset of this litigation, the Court made clear that general causation would be addressed on a centralized track, early, globally, and on a fixed timeline. The Court consistently reiterated that the general causation phase would be conclusive, and that only case-specific or “specific causation” issues would proceed thereafter. On **July 29, 2020**, the Court announced its intention to have “orders

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<sup>4</sup> See *S. States Rack & Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592, 597 (4th Cir. 2003).

<sup>5</sup> *Fed. R. Civ. P.* 16(b)(3)(A).

<sup>6</sup> See *Derby v. Godfather’s Pizza, Inc.*, 45 F.3d 1212, 1215 (8th Cir. 1995); *Loggins v. Franklin Cnty.*, 218 F. App’x 466, 478 (6th Cir. 2007).

<sup>7</sup> *Fed. R. Civ. P.* 1.

governing general causation and expert reports on those issues” in place “by the end of the year.”<sup>8</sup>

This was reiterated on **September 30, 2020**, when the Court emphasized the need for a “parallel track” dedicated to general causation for both bodily injury and personal injury cases, stating that it intended “at the end of November, to enter an order governing discovery on the general causation/bodily injury claims.”<sup>9</sup>

By **November 24, 2020**, the Court had laid out a full schedule:

- Plaintiffs’ general causation expert reports due by May 1, 2021
- Defense general causation reports due by the end of May
- *Daubert* motions by the end of August
- Replies by November 1, 2021
- Hearings to follow shortly thereafter.<sup>10</sup>

This schedule was formalized in a series of binding case management orders with firm deadlines:

- **CMO 22 (Nov. 25, 2020):** Defense expert deadline: July 1, 2021;

*Daubert* motions: August 31, 2021.<sup>11</sup>

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<sup>8</sup> ECF No. 636, Hr’g Tr. at 46:1–7 (July 29, 2020).

<sup>9</sup> ECF No. 586, Hr’g Tr. 49:4–25 (Sept. 30, 2020).

<sup>10</sup> ECF No. 643, Hr’g Tr. 14:11–15:2 (Nov. 24, 2020).

<sup>11</sup> ECF No. 640, Case Mgmt. Order No. 22 (Nov. 25, 2020).



- **Revised CMO 22 (Jan. 11, 2021):** Defense expert deadline: June 1, 2021.<sup>12</sup>
- **Special Master Order No. 2 (Feb. 4, 2021):** Extended all deadlines by 60 days, but stated they “will not be extended” again absent “compelling and necessitous circumstances.”<sup>13</sup>
- **CMO 23 (Feb. 11, 2021):** Final defense expert deadline: August 2, 2021; Final *Daubert* deadline: **November 1, 2021**.<sup>14</sup>

After the general causation deadlines passed, the Court addressed the finality of those cutoffs in a **July 28, 2021** hearing. The issue arose when a non-leadership firm submitted its own general causation experts outside the established process. Then Defendant’s argued, and the Court made clear that the time to submit such reports had already passed:

“There must be some meaning to these expert deadlines, Your Honor. I mean, the deadline for plaintiffs to disclose their general causation expert came and went.”<sup>15</sup>

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<sup>12</sup> ECF No. 726, Revised Case Mgmt. Order No. 22 (Jan. 11, 2021).

<sup>13</sup> ECF No. 843, Special Master Order No. 2 (Feb. 4, 2021).

<sup>14</sup> ECF No. 863, Case Mgmt. Order No. 23 (Feb. 11, 2021).

<sup>15</sup> ECF No. 1429, Hr’g Tr. at 20:6–7 (July 28, 2021).

At the **January 5, 2022** and **February 28, 2022** conferences, the Court confirmed that the general causation *Daubert* hearings were being scheduled and concluded at that time.

**Jan. 5, 2022:** “We expect the final papers on the *Daubert* motions to be filed this week... Any *Daubert* hearings we need will take place in late February, early March.”<sup>16</sup>

**Feb. 28, 2022:** “These *Daubert* motions are all going to be decided by the middle of March. They will be all done.”<sup>17</sup>

Taken together, the Court clearly limited general causation disclosures to the timeframe established in Case Management Orders 22 and 23, with **November 1, 2021** as the final deadline for service of defense expert reports on general causation.<sup>18</sup> Any attempt to reintroduce general causation opinions now, years after the close of that phase, directly contradicts the Court’s Orders.

### **ARGUMENT**

Dr. Diette’s report must be excluded under Rules 16(f) and 37(c)(1), and the Court’s case management orders, because it is untimely, unjustified, and prejudicial. It surprises Plaintiffs, disrupts the MDL schedule, delays trial preparation, and offers

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<sup>16</sup> ECF No. 1848, Hr’g Tr. at 19:2–7, 20:7–11 (Jan. 5, 2022).

<sup>17</sup> ECF No. 1946, Hr’g Tr. at 39:21–40:1, 41:3–12, 43:2–8, 44:16–25 (Feb. 28, 2022).

<sup>18</sup> ECF No. 640, Case Mgmt. Order No. 22 (Nov. 25, 2020); ECF No. 863, Case Mgmt. Order No. 23 (Feb. 11, 2021).

no way to cure the resulting harm. His disclosure is untimely and offers general causation opinions well after the deadline for such opinions has passed. The Court has repeatedly emphasized the importance of adhering to a structured and centralized process for managing general causation evidence in this MDL. Allowing this late-disclosed report would disrupt that schedule and prejudice Plaintiffs who have litigated this case in reliance on the finality of those deadlines.

In the MDL context, strict adherence to scheduling orders is critical. Where a party fails to diligently meet deadlines, reopening discovery months later undermines the orderly administration of the case.<sup>19</sup> MDLs present unique challenges requiring strict compliance with case management orders. Courts routinely exclude general causation experts disclosed outside the authorized schedule. In *In re Zolof (Sertraline Hydrochloride) Prods. Liab. Litig.*, the court excluded an untimely expert report submitted in an MDL proceeding, emphasizing that the failure to timely disclose was neither substantially justified nor harmless because allowing such testimony would subvert the Zolof MDL's scheduling structure and disrupt coordinated resolution of the litigation.<sup>20</sup> The court emphasized that late expert disclosures cannot be permitted to circumvent a carefully constructed

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<sup>19</sup> *Lexington Ins. Co. v. Scott Homes Multifamily, Inc.*, No. CV-12-02119, 2016 WL 4492296, at \*5 (D. Ariz. Aug. 26, 2016).

<sup>20</sup> *In re Zolof (Sertraline Hydrochloride) Prods. Liab. Litig.*, 176 F. Supp. 3d 483, 493 (E.D. Pa. 2016).

discovery process.<sup>21</sup> Similarly, in *In re C.F. Bean LLC*, the Fifth Circuit affirmed the exclusion of expert testimony where new opinions were offered after the deadline, noting the importance of maintaining finality in complex litigation.<sup>22</sup> When a party fails to comply with the court’s expert disclosure schedule without substantial justification or clear harmlessness, exclusion is the appropriate remedy.

Under Rule 37(c)(1), a party that fails to timely disclose expert evidence is precluded from using that expert “unless the failure was substantially justified or is harmless.”<sup>23</sup> Courts apply a five-factor test to evaluate whether a failure to disclose meets that narrow exception, considering: “(1) the surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure the surprise; (3) the potential for disruption of the trial; (4) the explanation for the failure to disclose; and (5) the importance of the evidence.”<sup>24</sup> ***All five factors weigh strongly in favor of exclusion here.***

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<sup>21</sup> *Id.*

<sup>22</sup> *In re C.F. Bean LLC*, 841 F.3d 365, 369–70 (5th Cir. 2016).

<sup>23</sup> Fed. R. Civ. P. 37(c)(1).

<sup>24</sup> *S. States Rack & Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592, 597 (4th Cir. 2003); *Rambus, Inc. v. Infineon Techs. AG*, 145 F. Supp. 2d 721, 726 (E.D. Va. 2001).

**A. The Purported Importance of Dr. Diette’s Opinions Cannot Override  
the Prejudice and Procedural Violation**

*First*, while Defendants may argue that Dr. Diette’s opinions are ostensibly important, this factor cannot outweigh the prejudice, surprise, and disruption caused by the late disclosure. Further, the purported importance of his opinion cannot outweigh the Court’s express directive that general causation had to be completed as a foundational matter. In fact, the Court noted that resolving general causation was “the first and most important question here.”<sup>25</sup> General causation has already been addressed under the schedule and procedures the Court set forth. To permit further general causation evidence now would be to relitigate an issue the Court has already declared closed. Moreover, Dr. Diette’s opinions are cumulative and duplicative of those offered by other defense experts during the proper general causation phase and are not necessary to resolve any outstanding issue specific to Mr. Roberts.

Dr. Diette confirmed during his deposition that his expert report, submitted under the caption of Mr. Roberts’ case, does not mention Mr. Roberts by name.<sup>26</sup> When asked, he acknowledged that he did not review Mr. Roberts’ medical records in detail, did not examine Mr. Roberts’ prescription history, and did not read the testimony of Mr. Roberts’ treating or prescribing physicians.<sup>27</sup> Dr. Diette conducted

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<sup>25</sup> ECF No. 1946, Hr’g Tr. at 41:6–7 (Feb. 28, 2022).

<sup>26</sup> Ex. B – Diette Dep. Tr. at 10:6–11.

<sup>27</sup> Ex. B – Diette Dep. Tr. at 10:12–11:13

no individualized analysis of Mr. Roberts' condition and instead relied solely on general scientific literature and summaries from other experts. As such, Dr. Diette's opinions plainly concern general causation, not specific causation, and fall outside the permissible scope at this stage of the litigation.

Dr. Diette's own testimony further confirms that his report and opinions are overwhelmingly directed toward general causation, not Mr. Roberts specifically. When asked whether he offered any opinions specific to Mr. Roberts, Dr. Diette responded, "Not yet," and later admitted, "I'd say there's one opinion that might be specifically about him. But otherwise, I would say they're all general."<sup>28</sup> He identified only a single opinion related to Mr. Roberts, concerning latency, that simply questioned whether the time between ingestion and diagnosis was consistent with general scientific literature. When asked directly whether he planned to offer any other case-specific opinions, Dr. Diette answered, "I don't plan to."<sup>29</sup> This testimony confirms that Dr. Diette is not offering proper specific causation analysis and is instead attempting to relitigate general causation, contrary to this Court's prior orders and long-closed deadlines.

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<sup>28</sup> Ex. B – Diette Dep. Tr. at 11:18–12:10.

<sup>29</sup> Ex. B – Diette Dep. Tr. at 12:22–13:1.

Further, as the *Southern States* court emphasized, “[i]mportance of the evidence cannot override the enforcement of local rules and scheduling orders.”<sup>30</sup>

**B. Allowing Dr. Diette’s Report Would Disrupt the MDL Schedule and Undermine the Court’s Case Management Structure**

*Second*, allowing Dr. Diette’s report and testimony would significantly disrupt the progress of this MDL, and delay efforts to have Mr. Roberts’ case ready for trial by September. As the Court has reiterated, general causation issues were to be addressed globally, in a defined window, and resolved early in the litigation to better streamline such complex scientific issues. At the February 28, 2022 conference, the Court made the Court’s intent clear: “These *Daubert* motions are all going to be decided by the middle of March. They will be all done.”<sup>31</sup> Reopening that process now would undermine the efficiencies the Court carefully created in the litigation early on. Reintroducing general causation at this late stage would undermine the Court’s goal of reaching finality and further delay the resolution of both class and individual claims. In complex MDLs, courts routinely exclude untimely expert reports for precisely this reason.<sup>32</sup>

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<sup>30</sup> *S. States*, 318 F.3d at 598.

<sup>31</sup> ECF No. 1946, Hr’g Tr. at 40:1 (Feb. 28, 2022).

<sup>32</sup> *See, e.g., In re Zolof (Sertraline Hydrochloride) Prods. Liab. Litig.*, 176 F. Supp. 3d 483, 493 (E.D. Pa. 2016) (excluding late expert where disclosure “would subvert the MDL’s scheduling orders and disrupt the litigation”).

**C. Defendants Have No Justification for Failing to Timely Disclose Dr.**

**Diette**

*Third*, Defendants offer no justification for disclosing a new general causation expert nearly four years after the deadline was first proposed and over three years after it was enforced. The failure to identify Dr. Diette earlier is not due to newly discovered evidence or changed circumstances. There is no indication that new evidence came to light or that his opinions could not have been developed and disclosed in accordance with the original expert schedule. Courts have consistently found that oversight or strategic delay is not a sufficient reason to bypass a Rule 26 or scheduling order deadline.<sup>33</sup>

**D. The Disclosure of Dr. Diette's Report Comes as a Complete Surprise to Plaintiffs**

*Fourth*, the disclosure of Dr. Diette's report comes as a complete surprise to Plaintiffs. The Court established a clear schedule beginning as early as July 2020, when the Court announced that "by the end of this year we'll have in place orders governing general causation and expert reports on those issues."<sup>34</sup> Case Management Order 23 fixed August 2, 2021, as the deadline for defense general causation expert

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<sup>33</sup> See *Trulock v. Freeh*, 275 F.3d 391, 402 (4th Cir. 2001) (affirming exclusion of evidence not disclosed under Rule 26 where party had "ample opportunity" to do so).

<sup>34</sup> ECF No. 636, Hr'g Tr. at 46:4–6 (July 29, 2020).



reports.<sup>35</sup> There is no ambiguity as to the scope or effect of that order. The Court clearly limited general causation disclosures to the timeframe established in Case Management Orders 22 and 23, with August 2, 2021 as the final deadline for service of defense expert reports on general causation.<sup>36</sup> Dr. Diette was never disclosed during that period and has not been previously identified as part of the coordinated general causation proceedings. His report, served in 2025, was not even contemplated in the existing expert structure and was made without any motion to modify the Court's scheduling orders.

#### **E. Plaintiffs Have No Meaningful Opportunity to Cure the Prejudice**

##### **Caused by the Untimely Disclosure**

*Fifth*, Plaintiffs have no reasonable way to cure the prejudice resulting from this late disclosure. The general causation phase has concluded, the *Daubert* process has run its course, and Plaintiffs have litigated and argued their expert theories based on the assumption that no new general causation experts would be introduced years later. Reopening expert discovery would impose significant costs, delay the resolution of the litigation, and upend the structure the Court carefully imposed to

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<sup>35</sup> ECF No. 863, Case Mgmt. Order No. 23 (Feb. 11, 2021)

<sup>36</sup> ECF No. 640, Case Mgmt. Order No. 22 (Nov. 25, 2020); ECF No. 863, Case Mgmt. Order No. 23 (Feb. 11, 2021).

streamline proceedings. Dr. Diette was not disclosed during the general causation phase and his report was not subject to *Daubert*.

Further, Rule 16(f) independently authorizes exclusion of expert testimony as a sanction for failing to comply with a scheduling order.<sup>37</sup> The Court set binding deadlines for general causation disclosures, affirmed multiple times over the course of status conferences and in its orders.<sup>38</sup> No such circumstances are present here, and allowing this disclosure would render the Court's prior directives meaningless.

In short, Dr. Diette's report is untimely, improper, and prejudicial. It offers general causation opinions that are barred by the Court's prior rulings and the Federal Rules of Civil Procedure. Defendants cannot show that their late disclosure was either substantially justified or harmless, thus exclusion is required under Rule 37(c)(1), Rule 16(f), and consistent MDL precedent.

### **CONCLUSION**

In conclusion, because Dr. Diette's opinions are untimely, his report and testimony must be excluded in its entirety.

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<sup>37</sup> *Fed. R. Civ. P.* 16(f)(1)(C).

<sup>38</sup> See, e.g., ECF No. 863, Case Mgmt. Order No. 23 (Feb. 11, 2021) (setting Aug. 2, 2021 as the deadline for defense expert reports); ECF No. 843, Special Master Order No. 2 (Feb. 4, 2021).

Respectfully submitted,

By: /s/ Daniel Nigh

Daniel Nigh, Esq.  
NIGH GOLDENBERG RASO &  
VAUGHN, PLLC  
*Attorneys for Plaintiffs*  
14 Ridge Square NW  
Third Floor  
Washington, D.C. 20016  
Tel: 202-792-7927  
Fax: 202-792-7927  
Email: [dnigh@nighgoldenberg.com](mailto:dnigh@nighgoldenberg.com)

**CERTIFICATE OF SERVICE**

I hereby certify that on May 22, 2025, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notifications of such filing to the CM/ECF participants registered to receive service in this MDL.

By: /s/ Daniel Nigh

Daniel Nigh, Esq.